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| 09/542,445      | 04/04/2000  | Mark A. Staples      | BEH-7354A-Div       | 5919             |

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12/31/2002

Lois K Ruzala  
c/o Dade Behring Inc  
1717 Deerfield Rd #778  
Deerfield, IL 60015-0778

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/542,445

Applicant(s)

Staples et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 7, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 ~~is/are~~ rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **Request for Continued Examination**

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 10/07/02 (paper no. 14) has been entered.

### **Status of Claims**

2) Claims 4-39 have been canceled via the amendment filed 06/07/01.  
Claims 1-3 are pending and are under examination.

### **Prior Citation of Title 35 Sections**

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Maintained**

5) The objection to the specification made in paragraph 7(b) of the Office Action mailed 09/04/01 (paper no. 9) is maintained for reasons set forth therein. Applicants have requested previously that amendments to the trademark recitations be done via an Examiner's amendment after the indication allowable subject matter.

### **Specification**

6) The amendment to the abstract filed 01/02/02 (paper no. 11) is objected to under 35 U.S.C. § 132, because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. In the last line of the abstract, Applicants have added the limitation "benzoic acid derivative". However, it does not appear that this limitation has support in the specification as originally filed. Applicants have not pointed to a

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specific part of the disclosure which provides descriptive support for this new limitation. Applicants are required to cancel the new matter in response to this Office Action, or point to specific page number(s) and line number(s) where one can find support for the limitation.

**Rejection(s) Withdrawn**

7) The rejection of claims 1-3 made in paragraph 11 of the Office Action mailed 04/05/02 (paper no. 12) under 35 U.S.C § 103(a) as being unpatentable over Nishijo *et al.* (*Chem. Pharm. Bull.* 33: 2648-2653, 1985, already of record) or Kaufman *et al.* (CA 2,014,233 - Applicants' IDS) in view of Neumann *et al.* (US 4,559,291, already of record) or Khanna *et al.* (US 4,798,804, already of record), is withdrawn. Applicants are asked to note the rejection(s) made below.

**Rejection(s) Maintained**

8) The rejection of claims 1-3 made in paragraph 8(a) of the Office Action mailed 09/04/01 (paper no. 9) under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the US patent 6,171,801, is maintained for reasons set forth therein. Applicants have assured the Office that they will file a terminal disclaimer once the claimed deemed allowable.

9) The rejection of claims 1-3 made in paragraph 8(b) of the Office Action mailed 09/04/01 (paper no. 9) under the judicially created doctrine of obviousness-type double patenting over claims 1, 2, 4, 5, 10, 11, 26 and 27 of the patent, US 6,159,698, is maintained for reasons set forth therein. Applicants have assured the Office that they will file a terminal disclaimer once the claims are deemed allowable.

**Rejection(s) under 35 U.S.C. § 103**

10) Claims 1-3 are rejected under 35 U.S.C § 103(a) as being unpatentable over Tabachnick *et al.* (*Arch. Biochem. Biophys.* 136: 467-479, 1970) in view of Khanna *et al.* (US 4,798,804, already of record).

The use of the transitional phrase "comprising" in claim 1 has been noted. Such a transitional term used in a claim defines the scope of that claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is

inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). See M.P.E.P. 2111.03 [R-1]. In the instant case, the “comprising” language of the claimed invention does not preclude additional methods steps being a part of the claimed method. Therefore, the instantly claimed method is not limited to a single step process.

Tabachnick *et al.* teach a method for releasing or displacing thyroxine (i.e., a ligand) from a complex with human serum albumin (i.e., endogenous protein) by contacting a medium containing the complex with an effective amount of a substituted benzoic acid derivative, including an *ortho* substituent. The substituent contains an alkyl group CH<sub>3</sub> (see abstract; Materials and Methods; Results; Table I and IV; Figure 5; and pages 476 and 478).

Tabachnick *et al.* do not expressly teach the use of the specific benzoic acid substituent species recited in the instant claims.

However, the conventional use of the specific substituted benzoic acid, methoxybenzoic acid, was well known in the art at the time of the instant invention. Khanna *et al.* taught methoxybenzoic acid to be a releasing agent for releasing a ligand from a complex (see the abstract; and column 3, lines 35-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace Tabachnick’s substituted benzoic acid releasing agent with Khanna’s specific methoxybenzoic acid releasing agent to produce the method of the instant invention, with a reasonable expectation of success. Substitution of one substituted benzoic acid releasing agent with an alternate art-known specific benzoic acid substituent releasing agent would have been well within the realm of routine experimentation and would have been obvious to one of skill in the art, since the latter was already taught by Khanna *et al.* to serve as a conventionally used releasing agent.

Claims 1-3 are *prima facie* obvious over the prior art of record.

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**Remarks**

**11)** Claims 1-3 stand rejected.

**12)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

**13)** Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December, 2002

  
**S. DEVI, PH.D.**  
**PRIMARY EXAMINER**